



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2020-0015]

RIN 0651-AD46

Disclaimer Practice in Patents and Patent Applications

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO) proposes to amend the rules of practice to expand when certain types of patent applicants and patentees may, subject to other conditions, obtain or enforce a second patent for an invention that is similar (i.e., patentably indistinct) to a first patent. Ordinarily, in examination before the USPTO, any application for a second patent covering such similar invention would be rejected. The proposed rule change is limited to the situation where owners of the first and second patents or patent applications are different but have an agreement to conduct research together (i.e., a joint research agreement). For this limited situation, the proposed rule change would increase the ability to file a document, called a terminal disclaimer, that ties the rights of a second patent to the first patent. Specifically, a terminal disclaimer causes the second patent to limit its enforceable patent term to end no later than the first patent's term and limits when the second patent can be enforced. The proposed rule change would expand when a terminal disclaimer is permitted to be filed in the joint research agreement situation by eliminating the requirement that the second patent or patent application be filed later than the first patent or patent application. The USPTO also proposes to amend its rules of practice to explicitly state existing

practices in the rules regarding when certain affidavits and declarations, as well as terminal disclaimers, may be filed.

DATES: Comments must be received by March 22, 2021 to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at <https://www.regulations.gov>. To submit comments via the portal, one should enter docket number PTO-P-2020-0015 on the homepage and click “search.” The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this notice and click on the “Comment Now!” icon, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by email at Susy.Tsang-Foster@uspto.gov; or Robert Clarke, Editor, Manual of Patent Examining Procedure, Office of the Deputy Commissioner for Patent Examination Policy, by email at Robert.Clarke@uspto.gov.

SUPPLEMENTARY INFORMATION: Patent applications and patents are subject to the doctrine of nonstatutory double patenting to prevent both the unjust timewise extension of the right to exclude and multiple infringement suits by different parties.

These situations may arise from the granting of multiple patents with patentably indistinct claims where the patents have a common owner, applicant, or inventor or where the patents are not commonly owned but are subject to a joint research agreement. Double patenting analysis is not limited to situations in which the reference patents or applications, whose claims form the basis for the nonstatutory double patenting rejection, are prior art as defined in 35 U.S.C. 102. The reference may have an effectively filed date that is before, the same as, or after the effective filing date of a claimed invention in an application under examination or patent under reexamination (i.e., the subject patent application or patent). Thus, the reference need not be “prior art” to the claimed invention in the subject application or patent for its claims to be relied upon in a nonstatutory double patenting rejection. For more information on the nonstatutory double patenting doctrine, see section 804 of the Manual of Patent Examining Procedure (Ninth Edition, Revision 10.2019, June 2020).

I. Background: *A. Joint Research Agreements:* The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act), Pub. L. 108-453, 118 Stat. 3596, was passed to promote cooperative research between universities, the public sector, and private enterprises. The CREATE Act amended 35 U.S.C. 103(c), effective on December 10, 2004, to provide that subject matter developed by another person and a claimed invention shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of excluding prior art usable in obviousness rejections if three conditions are met: (1) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for

patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

The legislative history recognized that the CREATE Act would result in two or more patents being issued to patentably indistinct inventions, and called upon the nonstatutory double patenting doctrine to protect the public from multiple enforcement actions based on patents issued due to the passage of the CREATE Act. *See* H.R. Rep. No. 108-425, at 6 (2003) (stating that a terminal disclaimer is required “when double patenting is determined to exist for two or more claimed inventions” for any application for which the applicant takes advantage of the “safe harbor” provision in [pre-AIA] 35 U.S.C. 103(c) as amended by the CREATE Act). Consistent with the legislative history, the nonstatutory double patenting doctrine was expanded to include rejections based on patents or patent applications that were disqualified as prior art under pre-AIA 35 U.S.C. 103(c).

A prior art exception, similar to the prior art exclusion in the CREATE Act, was enacted in 35 U.S.C. 102(b)(2)(C) and 102(c) by the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011). Consistent with this prior art exception, the nonstatutory double patenting doctrine was further revised to include rejections based on patents or patent applications that were excepted as prior art under 35 U.S.C. 102(b)(2)(C) and 102(c).

B. Current Practice: A nonstatutory double patenting rejection may be obviated, in most circumstances, by filing a terminal disclaimer. Under current USPTO regulations, two types of terminal disclaimers may be used to obviate nonstatutory double patenting rejections. The first type is filed pursuant to 37 CFR 1.321(c) and must include a provision that the subject patent or any patent issuing from the subject patent application

shall be enforceable only for and during the time period that the subject patent or any patent issuing from the subject patent application is commonly owned with the reference that is the basis of the nonstatutory double patenting rejection. The second type is filed pursuant to 37 CFR 1.321(d) and must include a provision that the subject patent or any patent issuing from the subject patent application shall be enforceable only for and during such period that the subject patent or any patent issuing from the subject patent application and the reference are not separately enforced. The second type obviates nonstatutory double patenting based on a non-commonly owned reference that is disqualified or excepted as prior art as a result of activities undertaken within the scope of a joint research agreement.

Currently, 37 CFR 1.321(d) limits the ability of parties to a joint research agreement to file a terminal disclaimer to overcome a nonstatutory double patenting rejection to instances where the reference application or patent had previously been applied as prior art or was available as prior art against the subject application or patent and the reference application publication or patent had been excepted or disqualified respectively as prior art under 37 CFR 1.104(c)(4)(ii) or (c)(5)(ii). *See Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004*, 70 FR 54259, 54262 (Sept. 14, 2005). 37 CFR 1.321(d) does not provide for the filing of such a terminal disclaimer where the reference is not prior art under 35 U.S.C. 102(a)(2) or pre-AIA 35 U.S.C. 102(e) and therefore cannot be excepted or disqualified as prior art as set forth in 37 CFR 1.104(c)(4)(ii) or (c)(5)(ii). For example, a reference is not prior art where the effective filing date of the claimed invention in the subject application or patent is the same as or before the effectively filed date of the reference. Because of this limitation, the USPTO has granted a number of petitions requesting a waiver of the prior art requirement in 37 CFR 1.321(d). Another example where the reference is not prior art under 35 U.S.C.

102(a)(2) or pre-AIA 35 U.S.C. 102(e) is where the inventive entities are the same for the reference and the subject application or patent.

C. Recent Judicial Change: In 2014, the U.S. Court of Appeals for the Federal Circuit clarified for patents subject to the 20-year patent term that a first patent that expires before a second patent to a common owner or inventor may be used as a reference in a nonstatutory double patenting rejection, regardless of whether the first patent is prior art to the second patent. See *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014). Following *Gilead*, applicants that received a nonstatutory double patenting rejection based on an application or a patent under a joint research agreement that was not earlier filed than the application under examination have filed petitions under 37 CFR 1.183 seeking waiver of the requirement in current 37 CFR 1.321(d) that the reference in a terminal disclaimer be prior art in order to file a terminal disclaimer under 37 CFR 1.321(d). In the last two years, the USPTO has received petitions under 37 CFR 1.183 to waive such requirement of 37 CFR 1.321(d) in 26 applications. In 22 of the 26 applications the petitions have been granted. In four of the 26 applications, the petitions were dismissed either because the terminal disclaimer or the petition failed to comply with the requirements of 37 CFR 1.321(d) or 37 CFR 1.183. Each of these dismissals and the impact of the proposed rule is discussed in more detail below. The proposed rule would not have the same impact on these four applications because the facts for each application are different. On the whole, in view of the routine granting of petitions to waive the prior art requirement in the current regulations over the last two years, the Office has determined that this proposed rule would be beneficial to avoid the unnecessary costs and delays incurred by users with the current petition process.

In two applications the petitions were dismissed because the offered terminal disclaimers failed to comply with all of the other requirements of 37 CFR 1.321(d). If these had been filed under the proposed rule, there would be no change as to the initial disapproval of these terminal disclaimers as the other requirements of 37 CFR 1.321(d) still must be met. The only change in this scenario under the proposed rules would be that a petition would not have been required—a proper terminal disclaimer will be accepted without the need for a petition. Moving forward in these applications, a *proper* terminal disclaimer would be accepted in any renewed petition (or depending on the timing, without a renewed petition if it occurs under the proposed rules). In one of the applications, for example, a renewed petition has been filed and if the revised terminal disclaimer is determined to be proper, the renewed petition will be granted. No action has been taken in the other application to rectify the errors in the terminal disclaimer.

In the other two applications where petitions were dismissed, the dismissals were the result of petitioners' failure to set forth an extraordinary situation within the meaning of 37 CFR 1.183 that would warrant waiver of the prior art requirement in 37 CFR 1.321(d). In both applications, the petitions failed to state the existence of any extraordinary situation as required by the language of 37 CFR 1.183. Under the proposed rule, should another applicant in a similar situation file a terminal disclaimer that complies with all of the requirements of proposed 37 CFR 1.321(d), the disclaimer would be accepted without the need for a grantable petition under 37 CFR 1.183. Moving forward in these applications, if a renewed petition provides the proper showing, the request to waive the prior art requirement in the rule will be granted and concurrently filed terminal disclaimers that comply with all of the other requirements in 37 CFR 1.321(d) will be accepted. In one of the applications, a renewed petition has been filed

II. Proposed Changes: *A. Changes to Current Practice:* The USPTO proposes to revise 37 CFR 1.321(d) to permit a terminal disclaimer filed by a party to a joint research agreement to obviate nonstatutory double patenting even where the patent application or patent referenced in the terminal disclaimer is not prior art under 35 U.S.C. 102 with respect to the subject application or patent in which the disclaimer is filed. This change would accommodate the two non-prior art circumstances discussed above in which a reference would not qualify as prior art under 35 U.S.C. 102(a)(2) or pre-AIA 35 U.S.C. 102(e). This change, permitting a party to a joint research agreement to file a terminal disclaimer even where the reference is not prior art, is consistent with the purpose of the CREATE Act as stated in its legislative history. Note that this change does not obviate the requirement in pre-AIA 35 U.S.C. 103(c) or in 35 U.S.C. 102(c) that the claimed invention of the application or patent in which the terminal disclaimer is filed was made as a result of activities undertaken within the scope of the joint research agreement.

The USPTO is further proposing to revise 37 CFR 1.321 such that it will no longer be applicable to an owner of a sectional interest in a patent. A sectional interest allows for the exercise of the exclusive patent rights in a specified part or portion of the United States. *See Potter v. Holland*, 4 Blatchf. 206, 19 F. Cas.1154, 1159 (1858) (discussing disclaimers by an owner of a sectional interest in a patent). While 35 U.S.C. 253 permits a disclaimer by an owner of a sectional interest, the assignment of a sectional interest is exceedingly rare; thus, to simplify the rule, the USPTO is proposing that a disclaimer by an owner of a sectional interest not be encompassed by 37 CFR 1.321. The USPTO proposes to address disclaimers by owners of a sectional interest via a petition under 37 CFR 1.182. The petition must clearly explain the extent of the disclaimant's interest in the patent and identify the complete claim(s) or term of a patent being disclaimed. This change will assist in preventing avoidable costs and delays to users due to the improper

filing of terminal disclaimers by a partial owner of an application or patent as an alleged sectional interest owner.

B. Changes Consistent with Current Practice: (1) When a Disclaimer May Be Filed: The USPTO proposes to revise 37 CFR 1.321 to explicitly provide that a terminal disclaimer may be filed to obviate a potential nonstatutory double patenting rejection or concern. Such disclaimer may be filed during the pendency of the application or after patent grant. The current practice of the USPTO is to accept terminal disclaimers that would overcome a potential nonstatutory double patenting rejection. Such preemptive terminal disclaimers avoid delays in examination resulting from the imposition of nonstatutory double patenting rejections. By revising the rule to be consistent with the current practice of accepting terminal disclaimers even when a nonstatutory double patenting rejection has not been made, the proposed change makes clear that patent applicants may file such disclaimers to avoid delays in examination.

A motion authorizing filing of a disclaimer must be granted before a disclaimer may be filed in an application or a patent involved in an interference under part 41 or administrative proceeding under part 42 before the Patent Trial and Appeal Board (Board). Also, where a terminal disclaimer is filed to overcome a nonstatutory double patenting issue in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file.

(2) Who May File a Disclaimer: Under proposed 37 CFR 1.321, a disclaimer in a patent may only be filed by the owner or owner(s) of the whole interest in the patent. Where more than one owner exists, the disclaimer may be filed as either a single document by all the owners of the whole interest in the patent or as several documents considered

together, wherein each document sets forth the extent of disclaimant's ownership interest in the patent and the total ownership interest accounts for 100% of the ownership interest. Similarly, where more than one applicant exists, a disclaimer may be filed as either a single document by all the applicants or as several documents considered together, wherein each document sets forth the extent of the disclaimant's ownership interest in the application and the total ownership interest accounts for 100% of the ownership interest. An assignee of record of an application filed before September 16, 2012, may execute a terminal disclaimer. In applications filed on or after September 16, 2012, an assignee of record of an application that is also the applicant of that application may execute a terminal disclaimer. For all applications and patents, regardless of the filing date, a patent practitioner of record may execute a terminal disclaimer.

Consistent with 35 U.S.C. 253, the USPTO proposes to refer to the party making the disclaimer in 37 CFR 1.321 as the "disclaimant" rather than the grantee, patentee, applicant, or assignee, as currently prescribed. The use of the common term to refer to the party making the disclaimer avoids confusion as to the proper party to file the paper regardless of when the terminal disclaimer was filed.

Consistent with the proposed change to explicitly permit the preemptive filing of a terminal disclaimer before a nonstatutory double patenting rejection is made, the USPTO is also proposing to revise 37 CFR 1.130 in an analogous manner. Specifically, in addition to the current practice in which an affidavit or declaration of attribution or prior public disclosure under the AIA is not filed until after rejection, the proposed change will explicitly permit an applicant or patent owner to file this type of affidavit or declaration to overcome a potential rejection of a claim over the reference, as is the current practice. If adopted, this proposed change to 37 CFR 1.130 would aid in the compact prosecution

of applications and reexamination proceedings by encouraging applicants and patent owners to preemptively file such an affidavit or declaration as they may already do under current practice.

III. Discussion of Specific Rules: The following is a discussion of proposed amendments to title 37 of the Code of Federal Regulations, part 1:

The USPTO proposes to amend § 1.130 by deleting “When any claim of an application or a patent under reexamination is rejected” in paragraphs (a) and (b). Paragraph (c) is proposed to be revised to change the two instances of “the rejection is based upon” to “the disclosure sought to be disqualified.”

The USPTO proposes to amend § 1.321 and to revise its title to limit its applicability to disclaimers in a patent or application by the owner of the whole interest.

The USPTO proposes to amend § 1.321(a) by adding the heading “Disclaimer of Any Complete Claim or Claims in a Patent” and moving the provisions concerning the filing of a terminal disclaimer in a patent to § 1.321(b)(1). Paragraph (a)(1) is proposed to be revised to replace “an attorney or agent of record” with “a patent practitioner of record.”

The requirement that the disclaimer include a provision that the disclaimer is binding upon the disclaimant and its successors and assigns has been moved from § 1.321(a) to new proposed § 1.321(a)(5). The reference to a patentee owning a sectional interest is also proposed to be removed from paragraph (a). Paragraph (a)(2), which currently applies to both a disclaimer of a complete claim or claims in a patent and a disclaimer of a term in a patent, is proposed to be revised to remove the sentence “A disclaimer which is not a disclaimer of a complete claim or claims, or term will be refused recordation.”

The language “refused recordation” in the current paragraph (a)(2) will not be included in the proposed § 1.321 because a disclaimer may be included in the USPTO’s record even if the regulatory requirements for a disclaimer have not been met. However, a disclaimer that does not meet the regulatory requirements in § 1.321 is ineffective and is not recorded as a disclaimer even if included in the application file. Accordingly, proposed paragraphs (a) (disclaimer of any complete claim or claims in a patent), (b)(1) (terminal disclaimer filed by a patentee), (b)(2) (terminal disclaimer in an application filed on or after September 16, 2012), and (b)(3) (terminal disclaimer in an application filed before September 16, 2012) state that the disclaimer must meet the requirements of proposed paragraphs (a)(1)-(5), (b)(1)(i)-(v), (b)(2)(i)-(v), and (b)(3)(i)-(v), respectively, to be effective. In addition, paragraphs (a)-(d) are proposed to be amended to state that only compliant disclaimers are recorded in the USPTO. Paragraph (a)(3) is proposed to be revised to add that the disclaimer must be made by the owner of the whole interest in the patent and to change “patentee’s ownership interest” to “disclaimant’s ownership interest.”

Section 1.321(b) is proposed to be revised to add the heading “Disclaimer or Dedication to the Public of the Entire Term or Any Terminal Part of the Term of a Patent or Any Patent to Be Granted on an Application.” The specific requirements for filing a terminal disclaimer in a patent are set forth in proposed § 1.321(b)(1); in applications filed on or after September 16, 2012, are set forth in proposed § 1.321(b)(2); and in applications filed before September 16, 2012, are set forth in proposed § 1.321(b)(3). This proposal eliminates the need for the public to consult § 1.321(b) in effect on September 15, 2012, when filing terminal disclaimers in an application filed before September 16, 2012.

Each proposed § 1.321(b)(1)-(3) includes parallel requirements in proposed subparagraphs (i)-(v) for filing a terminal disclaimer.

Proposed § 1.321(b)(1)(i) provides that a terminal disclaimer filed in a patent must be signed by the patentee or a patent practitioner of record. Similarly, proposed § 1.321(b)(2)(i) provides that a terminal disclaimer filed in an application filed on or after September 16, 2012, must be signed by the applicant or a patent practitioner of record and further specifies that a juristic entity who is the applicant may sign the terminal disclaimer. Proposed § 1.321(b)(3)(i) provides that a terminal disclaimer filed in an application filed before September 16, 2012, must be signed by the applicant where the application has not been assigned, the applicant and an assignee of record, where each owns an undivided interest in the application, the assignee of record of the whole interest in the application, or a patent practitioner of record.

Proposed § 1.321(b)(1)(ii) requires that the terminal disclaimer identify the patent and the term of the patent that is being disclaimed and further specifies that the terminal disclaimer must disclaim the entire term or any terminal part of the term of the patent. Similarly proposed § 1.321(b)(2)(ii) and (b)(3)(ii) require that the terminal disclaimer identify the application and the term of the patent to be granted that is being disclaimed and further specify that the terminal disclaimer must disclaim the entire term or any terminal part of the term of the patent to be granted.

Proposed § 1.321(b)(1)(iii) requires that the terminal disclaimer state the present extent of the disclaimant's ownership interest and that the terminal disclaimer be made by the patentee owning the whole interest in the patent. Similarly, proposed § 1.321(b)(2)(iii) and (b)(3)(iii) require that the terminal disclaimer state the ownership interest of the

disclaimant in the application and that the terminal disclaimer be made by the applicant owning the whole interest in the application.

Proposed § 1.321(b)(1)(iv), (b)(2)(iv), and (b)(3)(iv) require that the terminal disclaimer be accompanied by the fee set forth in § 1.20(d).

Proposed § 1.321(b)(1)(v), (b)(2)(v), and (b)(3)(v) require that the terminal disclaimer include a provision that the disclaimer is binding on the disclaimant and its successors and assigns.

Proposed § 1.321(c) adds the heading “Terminal Disclaimer with Common Ownership Enforcement Provision to Obviate Nonstatutory Double Patenting” and generally parallels current § 1.321(c). Proposed § 1.321(c) would explicitly provide for filing of a terminal disclaimer to obviate a potential nonstatutory double patenting rejection that has not yet been made. As is the case today, when a terminal disclaimer under proposed § 1.321(c) is filed to overcome a nonstatutory double patenting rejection in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file.

Proposed § 1.321(c)(1) incorporates the requirements of current § 1.321(c)(1) and (c)(2) which set forth the formal requirements and signature requirements for terminal disclaimers.

Proposed § 1.321(c)(2) revises the requirements of current § 1.321(c)(3) to provide that a terminal disclaimer under paragraph (c) must include a provision that the patent or any patent granted on the application for which the disclaimer is filed shall be enforceable only for and during such period that the patent or any patent granted on the application

for which the disclaimer is filed is commonly owned with the reference patent or any patent granted on the reference application whose claim(s) formed or may form the basis for the nonstatutory double patenting.

Proposed § 1.321(d) adds the heading “Terminal Disclaimer with a Joint Research Agreement Enforcement Provision to Obviate Nonstatutory Double Patenting.” The CREATE Act became effective on December 10, 2004, and AIA 35 U.S.C. 102(c) continued the intent of the CREATE Act. Therefore, proposed § 1.321(d) states that a terminal disclaimer filed under this paragraph is only available for patents granted on or after December 10, 2004, for reexamination proceedings of patents granted on or after December 10, 2004, and for applications pending on or after December 10, 2004.

Proposed paragraph (d)(1) revises the introductory text of § 1.321(d) to permit the filing of a terminal disclaimer by a party to a joint research agreement even if the reference application or patent on which the double patenting is based is not prior art to the application or patent in which the disclaimer is filed. Proposed § 1.321(d)(1) does so by removing the requirement that the reference patent or application was disqualified as prior art as set forth in either § 1.104(c)(4)(ii) or (c)(5)(ii). Specifically, proposed paragraph (d)(1) states that, subject to the requirements in proposed paragraph (d)(2), which establishes the existence of a joint research agreement, a terminal disclaimer may be filed in a patent, in a reexamination proceeding, or in a patent application to obviate nonstatutory double patenting or potential nonstatutory double patenting of a claimed invention based on a reference patent or application where the reference patent or application and the claimed invention are not commonly owned but are subject to a joint research agreement as defined by 35 U.S.C. 102(c) in effect on March 16, 2013 or 35 U.S.C. 103(c)(2) in effect on March 15, 2013. Proposed § 1.321(d)(1) also explicitly

provides for the filing of a terminal disclaimer to obviate a potential nonstatutory double patenting rejection that has not yet been made. As is the case today, when a terminal disclaimer under proposed § 1.321(d)(1) is filed to overcome a nonstatutory double patenting rejection in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file.

Proposed § 1.321(d)(1)(i) incorporates the requirements of current § 1.321(d)(1) and (d)(2) which set forth the formal requirements and signature requirements for terminal disclaimers.

Proposed § 1.321(d)(1)(ii) revises the requirements of current § 1.321(d)(3) to provide that a terminal disclaimer under proposed paragraph (d)(1) must include a provision waiving the right to separately enforce the patent or any patent granted on the application for which the disclaimer is filed and the reference patent or any patent granted on the reference application whose claim(s) formed or may form the basis for the nonstatutory double patenting, and agreeing that the patent or any patent granted on the application for which the disclaimer is filed shall be enforceable only for and during such period that the patent or any patent granted on the application for which the disclaimer is filed and the reference patent or any patent granted on the reference application are not separately enforced.

Proposed § 1.321(d)(2) sets forth the requirements to establish the existence of a joint research agreement in the patent, in the reexamination proceeding, or in the patent application, as applicable, for which the terminal disclaimer under proposed paragraph (d)(1) is filed.

Proposed § 1.321(d)(2)(i) sets forth the requirements for applications or patents subject to 35 U.S.C. 102 in effect on March 16, 2013, and parallels the requirements of current § 1.104(c)(4)(ii). Accordingly, if the requirements of § 1.104(c)(4)(ii) have already been met, there is no need to take further action to meet the requirements of proposed § 1.321(d)(2)(i).

Proposed § 1.321(d)(2)(ii) sets forth the requirements for applications or patents subject to 35 U.S.C. 102, in effect prior to March 16, 2013, and parallels the requirements of current § 1.104(c)(5)(ii). Accordingly, if the requirements of § 1.104(c)(5)(ii) have already been met, there is no need to take further action to meet the requirements of proposed § 1.321(d)(2)(ii).

Proposed § 1.321(e) provides that a disclaimer may not be entered into the official file of an application or a patent involved in an interference under subpart E of 37 CFR part 41 or any proceeding under 37 CFR part 42 unless a motion requesting to file the disclaimer under §§ 41.121(a)(2), 41.121(a)(3), or 42.20 is granted by the Board. If the disclaimer is inadvertently entered without the granting of the motion, the disclaimer will be expunged. The requirement is consistent with the current practice that limits when a disclaimer may be filed in a patent during certain proceedings before the Board.

IV. Rulemaking Requirements

A. Administrative Procedure Act: The changes proposed in this rulemaking involve rules of agency procedure and interpretation. *See Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 97 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001)

(Rule that clarifies interpretation of a statute is interpretive.); *Bachow Commc'ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes in this proposed rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 575 U.S. at 101 (Notice-and-comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))). However, the USPTO has chosen to seek public comment before implementing the rule to benefit from the public’s input.

B. Regulatory Flexibility Act: Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking, the agency must prepare and make available for public comment an Initial Regulatory Flexibility Analysis, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605.

Except in the extremely rare circumstance of the filing of a disclaimer by a sectional interest owner, this rulemaking does not propose to impose any additional requirements

or fees on applicants. This rulemaking eliminates the need for a small number of applicants each year to file a petition under 37 CFR 1.183 and pay an accompanying fee by authorizing the filing of a disclaimer by a joint researcher even if the reference patent or patent application is not prior art. This rulemaking does not propose to substantively change when an applicant may file a submission under 37 CFR 1.130 or a disclaimer under 37 CFR 1.321, although a petition under 37 CFR 1.183 accompanying the disclaimer may no longer be required. The changes proposed in this rulemaking will not have a significant economic impact on a substantial number of small entities because applicants continue to be entitled to file a disclaimer under 37 CFR 1.321 or submission under 37 CFR 1.130 if such filings are appropriate today. For the foregoing reasons, the changes proposed in this notice will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant under Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563. Specifically, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across

government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs):

This proposed rule is not expected to be an Executive Order 13771 (Jan. 30, 2017) regulatory action because this proposed rule is not significant under Executive Order 12866 (Sept. 30, 1993).

F. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

G. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

J. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

K. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

L. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes proposed in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995: The changes proposed in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by

State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 et seq.

N. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 et seq.

O. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

P. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to terminal disclaimers have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0031.

This rulemaking does not impose any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the USPTO is not resubmitting an information collection package to OMB for its review and approval

because the changes in this rulemaking do not affect the information collection requirements associated with the information collections approved under OMB control number 0651-0031 or any other information collection.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, the USPTO proposes to amend part 1 of title 37 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. In § 1.130, revise paragraphs (a), introductory text of paragraph (b), and (c) to read as follows:

§ 1.130 Affidavit or declaration of attribution or prior public disclosure under the Leahy-Smith America Invents Act.

(a) *Affidavit or declaration of attribution.* The applicant or patent owner may submit an appropriate affidavit or declaration to disqualify a disclosure as prior art by

establishing that the disclosure was made by the inventor or a joint inventor, or the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor.

(b) *Affidavit or declaration of prior public disclosure.* The applicant or patent owner may submit an appropriate affidavit or declaration to disqualify a disclosure as prior art by establishing that the subject matter disclosed had, before such disclosure was made or before such subject matter was effectively filed, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. An affidavit or declaration under this paragraph must identify the subject matter publicly disclosed and provide the date such subject matter was publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

* * * * *

(c) *When this section is not available.* The provisions of this section are not available if the disclosure sought to be disqualified was made more than one year before the effective filing date of the claimed invention. The provisions of this section may not be available if the disclosure sought to be disqualified is a U.S. patent or U.S. patent application publication of a patented or pending application naming another inventor, the patent or pending application claims an invention that is the same or substantially the same as the applicant's or patent owner's claimed invention, and the affidavit or declaration contends that an inventor named in the U.S. patent or U.S. patent application publication derived the claimed invention from the inventor or a joint inventor named in the application or patent, in which case an applicant or a patent owner may file a petition for a derivation proceeding pursuant to §§ 42.401 through 42.407 of this chapter.

* * * * *

3. Revise § 1.321 to read as follows:

§ 1.321 Disclaimers in a patent or an application by owner of the whole interest.

(a) *Disclaimer of any complete claim or claims in a patent.* A patentee owning the whole interest in a patent may disclaim any complete claim or claims in a patent. A notice of the disclaimer is published in the *Official Gazette* and attached to the printed copies of the specification. To be effective and recorded under this paragraph, the disclaimer must:

- (1) Be signed by the patentee or a patent practitioner of record;
- (2) Identify the patent and the complete claim or claims being disclaimed;
- (3) State the present extent of the disclaimant's ownership interest in the patent.

The disclaimer must be made by the owner of the whole interest in the patent;

- (4) Be accompanied by the fee set forth in § 1.20(d); and
- (5) Include a provision that the disclaimer is binding upon the disclaimant and its successors and assigns.

(b) *Disclaimer or dedication to the public of the entire term or any terminal part of the term of a patent or any patent to be granted on an application--*(1) *Terminal disclaimers or dedications filed by a patentee.* A patentee owning the whole interest in a patent may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted. A notice of the disclaimer is published in the *Official Gazette* and attached to the printed copies of the specification. To be effective and recorded under this paragraph, the terminal disclaimer must:

- (i) Be signed by the patentee or a patent practitioner of record;
- (ii) Identify the patent and the term of the patent that is being disclaimed. The terminal disclaimer must disclaim the entire term or any terminal part of the term of the patent;

(iii) State the present extent of the disclaimant's ownership interest in the patent. The terminal disclaimer must be made by the patentee owning the whole interest in the patent;

(iv) Be accompanied by the fee set forth in § 1.20(d); and

(v) Include a provision that the disclaimer is binding upon the disclaimant and its successors and assigns.

(2) *Terminal disclaimers or dedications in applications filed under 35 U.S.C. 111(a), 363, or 385 on or after September 16, 2012.* An applicant owning the whole interest in an application may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted. To be effective and recorded under this paragraph, the terminal disclaimer must:

(i) Be signed by the applicant or a patent practitioner of record. A juristic entity who is the applicant may sign the terminal disclaimer;

(ii) Identify the application and the term of the patent to be granted that is being disclaimed. The terminal disclaimer must disclaim the entire term or any terminal part of the term of the patent to be granted;

(iii) State the present extent of the disclaimant's ownership interest in the application. The terminal disclaimer must be made by the applicant owning the whole interest in the application;

(iv) Be accompanied by the fee set forth in § 1.20(d); and

(v) Include a provision that the terminal disclaimer is binding upon the disclaimant and its successors or assigns.

(3) *Terminal disclaimers or dedications in applications filed under 35 U.S.C. 111(a) or 363 before September 16, 2012.* An applicant and/or assignee of record owning the whole interest in an application may disclaim or dedicate to the public the entire term,

or any terminal part of the term, of a patent to be granted. To be effective and recorded under this paragraph, the terminal disclaimer must:

(i) Be signed:

(A) By the applicant where the application has not been assigned;

(B) By the applicant and an assignee of record where each owns an undivided part interest in the application;

(C) By the assignee of record of the whole interest in the application; or

(D) By a patent practitioner of record;

(ii) Identify the application and the term of the patent to be granted that is being disclaimed. A terminal disclaimer must disclaim the entire term or any terminal part of the term of the patent to be granted;

(iii) State the present extent of disclaimant's ownership interest in the application.

A terminal disclaimer must be made by the owner of the whole interest in the application;

(iv) Be accompanied by the fee set forth in § 1.20(d); and

(v) Include a provision that the disclaimer is binding upon the disclaimant and its successors and assigns.

(c) *Terminal disclaimer with common ownership enforcement provision to obviate nonstatutory double patenting.* Except as provided for in paragraph (d) of this section, a terminal disclaimer may be filed in a patent, in a reexamination proceeding, or in a patent application to obviate nonstatutory double patenting or potential nonstatutory double patenting of a claimed invention based on a reference patent or application. To be effective and recorded under this paragraph, the terminal disclaimer must:

(1) Comply with the provisions of paragraph (b)(1), (2), or (3) of this section as applicable; and

(2) Include a provision that the patent or any patent granted on the application for which the disclaimer is filed shall be enforceable only for and during such period that the

patent or any patent to be granted on the application for which the disclaimer is filed is commonly owned with the reference patent or any patent granted on the reference application whose claim(s) formed or may form the basis for the nonstatutory double patenting.

(d) *Terminal disclaimer with a joint research agreement enforcement provision to obviate nonstatutory double patenting.* This paragraph is only applicable for patents granted on or after December 10, 2004, reexamination proceedings of patents granted on or after December 10, 2004, and for applications pending on or after December 10, 2004.

(1) Subject to paragraph (d)(2) of this section, a terminal disclaimer may be filed in a patent, in a reexamination proceeding, or in a patent application to obviate nonstatutory double patenting or potential nonstatutory double patenting of a claimed invention based on a reference patent or application where the reference patent or application and the claimed invention are not commonly owned but are subject to a joint research agreement as defined by 35 U.S.C. 102(c) in effect on March 16, 2013 or 35 U.S.C. 103(c)(2) in effect on March 15, 2013. To be effective and recorded under this paragraph, the terminal disclaimer must:

(i) Comply with the provisions of paragraph (b)(1), (2), or (3) of this section as appropriate; and

(ii) Include a provision waiving the right to separately enforce the patent or any patent granted on the application for which the disclaimer is filed and the reference patent or any patent granted on the reference application whose claim(s) formed or may form the basis for the nonstatutory double patenting, and agreeing that the patent or any patent granted on the application for which the disclaimer is filed shall be enforceable only for and during such period that the patent or any patent granted on the application for which the terminal disclaimer is filed and the reference patent or any patent granted on the reference application are not separately enforced.

(2) A terminal disclaimer may be filed under paragraph (d)(1) of this section if the requirements of paragraph (d)(2)(i) or (ii), as applicable, have been met.

(i) For applications or patents subject to 35 U.S.C. 102 in effect on March 16, 2013.

(A) The applicant or patent owner provides, or has provided, a statement to the effect that the subject matter of the reference patent or application was developed and the claimed invention was made by or on behalf of one or more parties to a joint research agreement, within the meaning of 35 U.S.C. 100(h) and § 1.9(e), that was in effect on or before the effective filing date of the claimed invention, and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(B) The application for patent, or the patent, for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement in accordance with § 1.71(g).

(ii) For applications or patents subject to 35 U.S.C. 102 in effect prior to March 16, 2013.

(A) The applicant or patent owner provides, or has provided, a statement to the effect that the subject matter of the reference patent or application and the claimed invention were made by or on behalf of the parties to a joint research agreement, within the meaning of 35 U.S.C. 100(h) and § 1.9(e), that was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(B) The application for patent, or the patent, for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement in accordance with § 1.71(g).

(e) *Submission of a disclaimer during an interference under subpart E of part 41 or a proceeding under part 42.* A disclaimer of a complete claim or claims, or a disclaimer of the entire term or terminal part of the term (terminal disclaimer) under this section, of a patent involved in an interference under subpart E of part 41 of this chapter or a proceeding under part 42 of this chapter may not be entered into the official file or considered, or if inadvertently entered, will be expunged unless a motion requesting to file the disclaimer under §§ 41.121(a)(2), 41.121(a)(3), or 42.20 of this chapter has been granted.

Andrei Iancu,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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